UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL NO. 16-2738 (FLW) (LHG)**

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' STEERING COMMITTEE'S OBJECTION TO PROPOSED CASE MANAGEMENT ORDER OF THE SPECIAL MASTER RELATING TO DISCOVERY AND DEPOSITIONS

I. INTRODUCTION

On February 6, 2018, Special Master Joel A. Pisano, U. S. D. J. (Ret.), filed on the docket of this case a letter to counsel (the "Special Master letter") along with a Proposed "Case Management Order" (the "Proposed CMO") to govern discovery and depositions leading up to the disclosure of Plaintiffs' general causation expert reports. (*See* Special Master letter and Proposed CMO, Dkt Nos. 4173 and 4173-1, respectively).[1] The Special Master entered the Proposed CMO in response to discovery issues presented through letter briefing and argued during a January 22, 2018 discovery conference with the parties.[2] The Proposed CMO recommends that this Court rule that "to the extent that Plaintiffs desire to take depositions prior to completion of general causation expert reports, Plaintiffs may notice one Rule 30(b)(6)

[1] For the Court's convenience, a copy of the Special Master letter and Proposed CMO are attached hereto as Exhibit 1.

[2] A copy of the letter briefing and transcript of the January 22, 2018 arguments before the Special Master are attached hereto as Exhibits 2 through 5 for the Court's convenience and to make those documents part of the record of this objection. The transcript of the October 4, 2017 status conference before the Special Master is also attached hereto as Exhibit 6.

deposition per defendant, limited to the following subjects: a) composition of the Products; b) testing of the Products by Defendants; c) sampling of the Products by Defendants; and d) any influence or bias in the published scientific literature caused by Defendants." *Id.* at ¶3.

The PSC objects to this proposed ruling. The proposed ruling is simply inconsistent with the sound and efficient management of an MDL case of this complexity. This is a case of national import. Thousands of litigants' claims hinge on complex and disputed areas of science that have been the focus of academic investigation for decades. The case also involves claims relating to the causal nexus linking asbestos particles found in talcum products to ovarian cancer, an issue that has not received the same academic treatment. Despite mounting evidence to the contrary, Defendants have maintained over more than four decades that talcum power is safe and asbestos free—all the while waging a war against the science and crafting tests designed not to seek out the truth but to match their marketing.

Against this backdrop, the Proposed CMO plainly fails to ensure that discovery both adequate and proportional to the issues in dispute may be conducted before the PSC submits expert reports and proceeds to a *Daubert* hearing. This is a moment of critical importance in this litigation. If the Court enters the Proposed CMO, it will be doing what no other MDL court has done in comparable circumstances—*i.e.*, compelling plaintiffs to proffer expert reports and proceed to a hearing on general causation without the benefit of full and fair discovery. Under these circumstances, the PSC must object.

The simple fact of the matter is that if <u>now</u> is not the time to take the depositions of Defendants' fact witnesses, then there is no <u>appropriate</u> time to do so. As in most comparable MDL cases, defendant fact depositions go to the heart of general causation. Specific causation is inextricably interwoven with individual and bellwether plaintiff discovery. To deny Plaintiffs a

full and fair opportunity to discover their case before general causation reports are due is to turn the rulebook upside down.

Bifurcating this case into general and specific causation stages is not unusual in MDL cases like this and provided a sound approach to manage this case efficiently. But to the extent that decision was formed with a mind that the general causation field had already been plowed, it failed to account for the significant discovery on general causation issues that attends cases of this magnitude. Epidemiologic studies are important—but they are only part of the picture. Plaintiffs should not be denied the discovery tools necessary to firmly establish their case. [3]

[3] The PSC also objects to Paragraph 1 of the Proposed CMO denying the request for additional time to review documents. As noted in the letter briefing described in footnote 2 hereto, in December 2017 the PSC received a "document dump" of approximately 1 million pages of documents. Since the receipt of that production, the PSC has been diligently reviewing the documents. The manner of the production of those documents has caused problems in their review, e.g., production of documents previously produced but with new Bates numbers. This objection is therefore more in the nature of a reservation of rights, because Paragraph 5 of the Proposed CMO provides that the PSC's expert reports on general causation shall not be due until 45 days from the date the test results of the Samples are received. Since the test results of Samples will not be received for several months, the PSC should be able to continue to review Defendants' documents during the interim and incorporate findings in those documents within the expert reports their experts proffer. In fact, in this regard, the Special Master recognized in his explanatory letter, that a period will be needed to obtain the results of the Samples and, with expert reports not due until 45 days after the test results of the Samples are received, the PSC is afforded some additional time to continue its review of the documents.

However, the denial of additional time to review documents may handicap the PSC in taking depositions, depending on the speed with which the PSC can complete the document review process. For if depositions commence prior to the completion of the review of documents, it is possible that the PSC may be forced to take depositions with insufficient opportunity to review of all the relevant documents. The PSC is working on its review of the documents as quickly as possible. Further, at the recent February 7, 2018 Status Conference, the Court ordered the parties to negotiate the content of the notices for the Rule 30(b)(6) depositions and the parties continue to negotiate a proposed Deposition Protocol for the Court to approve. See Exhibit 7 (February 7, 2018 Status Conference transcript).

As a practical matter, the PSC believes it may be able to complete the document review process by the time the parties complete their negotiation of the content of the notices for the Rule 30 (b)(6) depositions and the terms of the Deposition Protocol, such that the proposed denial

II. Argument

A. Standard of Review

Federal Rule of Civil Procedure 53 sets forth the standard this Court must apply when reviewing a report and recommendation of a Special Master. *See* Fed. R. Civ. P. 53(f)(3)-(5). With respect to the Special Master's decisions, the Court "may adopt or affirm, modify, wholly or partly reject or reverse, or resubmit to the master with instructions." Fed. R. Civ. P. 53(f)(1). Rule 53(f) further provides that "[t]he court must decide *de novo* all objections to conclusions of law made or recommended by a master." Fed. R. Civ. P. 53(f)(4). Similarly, all objections to the master's findings of fact, unless the parties stipulate otherwise, are reviewed *de novo*. *See* Fed. R. Civ. P. 53(f)(3). "The Special Master's rulings on procedural matters are reviewed under the abuse of discretion standard." Fed. R. Civ. P. 53(f) (5).

Here, there has been no stipulation as to the standard of review. Therefore, pursuant to Rule 53(f)(3)-(5), The Special Master's findings of fact and conclusions of law should be reviewed *de novo.* Further, for the reasons set forth below, this Court should conclude that it was an abuse of discretion to limit the PSC in this matter to a single Rule 30(b)(6) deposition per defendant.

B. The PSC Requires a Fair and Reasonable Opportunity to Engage in Deposition Discovery

The PSC objects to the Special Master's finding that Plaintiffs are entitled to only one Rule 30(b)(6) witness per defendant, limited to four specific categories of information, prior to submission of Plaintiffs' general causation expert reports. The Special Master found that "one

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of additional time to review recently produced documents may not be meaningful and this issue may be moot. Nevertheless, for purposes of protecting the record, the PSC objects to the Special Master's recommendation that no additional time be afforded the PSC to complete its document review to the extent the denial of additional time prejudices the PSC. Thus, the PSC does not waive an objection to that portion of the Proposed CMO.

deposition per Defendant should suffice to provide Plaintiffs with information" necessary to the completion of general causation expert reports. *Id.* at p. 4.

The Special Master's letter and the accompanying Proposed CMO imply that fact depositions of specific current or former employees of defendants are not necessary to expert reports concerning general causation. As explained below, experts can permissibly rely upon evidence aside from the available statistical and epidemiological studies to inform their opinions as to general causation. By unfairly limiting number of depositions that the PSC may take under Rule 30(b)(6), the Special Master has placed an improper restriction on the PSC's ability to meet its initial burden as to general causation. *See Zellers v. NextTech Ne., LLC,* 533 Fed. Appx. 192, 196 (4th Cir. 2013) (explaining that in order to prove exposure to a specified substance caused a plaintiff's injury, plaintiffs must first prove levels of exposure that are hazardous to humans generally through relevant and reliable expert testimony).

The Court serves as a "gatekeeper" regarding expert testimony to ensure it is relevant and reliable. *See Daubert v. Merrell Dow Pharma., Inc.,* 509 U.S. 579, 113 S. Ct. 2786, 125 L.Ed.2d 469 (1993). Indeed, the question of if and when a *Daubert* hearing will occur in this case has been the topic of discussion at virtually every Status Conference since the first, with defendants arguing that the Court should dispense with discovery and proceed directly to the *Daubert* inquiry. Correctly so, the Court has resisted the temptation to follow Defendants' proposal, implicitly recognizing that the PSC is entitled to fair and reasonable discovery prior to requiring submission of their expert reports on general causation. At the moment, what is at issue is what would be a fair and reasonable balance to accommodate the needs of the PSC and their experts for information against the desires of Defendants to rush this case towards a *Daubert* inquiry. The Special Master's Proposed CMO, on its face, appears to undermine this balance.

Since ultimately *Daubert* will be an issue in this case, the PSC desires to confirm that the reports of its experts will meet the legal standard for admissibility. To do so, the experts need access to all relevant and pertinent information, particularly so that upon cross examination by Defendants during any deposition taken of them they are not exposed to a situation of not knowing some fact that could arm Defendants with an argument that challenges the expert's qualification or that the expert's opinion is not reliable or does not fit the case.

The criteria for the admissibility of an expert's report are set out in Federal Rule of Evidence 702, that incorporates three requirements for an admissible expert opinion: that the expert is "qualified," that the opinion is "reliable" and that the opinion "fits" the case and issues. *In re Diet Drugs Phentermine/Fenfluramine/Dexfenfluramine) Prod. Liab. Litig.*, 890 F. Supp. 2d 552, 560 (E.D. Pa. 2012) (citing *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008)). "[T]he test of reliability is flexible" and courts possess "broad latitude in determining reliability." *Id.* at 561 (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141-42, 119 S. Ct. 1167, 143 L.Ed.2d 238 (1999)).

Notably, *Daubert* does not require that evidence of statistical significance form the sole basis of an expert opinion regarding causation. *Matrixx Initiatives, Inc. v. Siracusano,* 563 U.S. 27, 41, 131 S. Ct. 1309, 179 L.Ed.2d 398 (2011). Yet, Defendants desire to pigeon-hole the PSC and its experts into expressing opinions based simply on published scientific articles, without regard to whether the articles may be the subject of bias or influence by industry or Defendants. Access to underlying information that Defendants possess, that may have never seen the light of day for scientists to evaluate, is necessary and important for the PSC's experts to evaluate.

The Supreme Court has recognized and numerous courts have acknowledged that medical/scientific professionals often base their reliable expert opinions on evidence other than

"statistical evidence from controlled clinical trials or epidemiological studies." *In re Diet Drugs*, 890 F. Supp. 2d at 561 (citing *Matrixx*, 131 S. Ct. at 1319). In fact, the Third Circuit has expressly stated, "we do not believe that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999).[4]

Further, as courts within the Third Circuit have recognized, "[e]pidemiological studies alone can only inform scientists that two events (*e.g.*, medication use and a [illness]) are associated." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Lit.*, 26 F. Supp. 3d 449, 454 (E.D. Pa. 2014), *recon. denied*, 2015 WL 314149 (E.D. Pa. Jan. 23, 2015). Once an association is established, scientists can then infer a causal relationship based on multiple factors, including factors that are commonly referred to as Bradford Hill factors. *Id.* at 454. These criteria include "strength of the association, consistency, specificity, temporality, coherence, biological gradient, plausibility, experimental evidence and analogy." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Lit.*, 858 F.3d 787, 795 (3d Cir. 2017).[5]

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[4] This discussion of *Daubert* is for general purposes only. Plaintiffs reserve their right to fully brief and address the *Daubert* standard as well as any future motions as the discussion above is not intended to be a full discussion of the *Daubert* issues in this case.

[5] A summary of the Bradford Hill criteria is as follows: Strength of association denotes "relative risk," meaning "the difference in risk of contracting a disease in people exposed to a risk factor, as compared to those not exposed (but otherwise similar)." *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 591 (D.N.J. 2002). Consistency means that the association has "been repeatedly observed by different persons, in different places, circumstances and times." A. Bradford Hill, The Environment and Disease: Association or Causation, 58 Proc. Royal Soc'y Med. 295, 296 (1965); *see also Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 718 n. 2 (Tex. 1997). Specificity generally holds that causation is likely when a specific population develops the same disease with no other likely cause; thus, consistent associations between specific exposures and clearly defined conditions. *See Merrell Dow Pharms., Inc.*, 953 S.W.2d at 718 n. 2; *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d 1345, 1361 (S.D. Fla. 2011) (stating that inconsistencies in a case definition limit the evidentiary value of the studies and that lack of a case definition is a deficiency). Temporality relates to the timing of the exposure

As the Third Circuit has recently explained, the Bradford Hill factors "are neither an exhaustive nor a necessary list," as an "expert can theoretically assign the most weight to only a few factors, or draw conclusion about one fact based on a particular combination of evidence." *Id.* at 796. However, as an expert's methodology must be reliable, in construing the Bradford Hill factors, "all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science." *Id.* (quoting *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002).

C. Principles of Proportionality Support the PSC's Request that it be Permitted to Take More Depositions and Engage in Greater Discovery than the Proposed CMO Appears to Be Authorizing

Rule 26 of the Federal Rules of Civil Procedure defines "the methods, scope, limits, and process of discovery." *Takacs v. Union Cty.*, No. CIVA 08-711-KSH-MAS, 2009 WL 3048471, at *1 (D.N.J. Sept. 23, 2009). Following the December 1, 2015 amendment, Rule 26 specifically requires "that the discovery be proportional to the needs of the case and take into account the

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and the onset of the disease. Hill, *supra* at 297. Biological gradient, or dose-response, is the relationship of the quantity of the substance exposed to (the dose) and the effect produced on the body (the response). *See In re Lip re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Prod. Liab. Litig.*, 174 F. Supp. 3d 911, 917 (D.S.C. 2016) (describing dose-response relationship as "meaning that any risk of diabetes is higher at higher doses of Lipitor"); *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1351 (explaining dose response in detail). Biological plausibility deals with the mechanisms by which disease develops in the body and by which the substance is processed in the body. Hill, *supra* at 298. Whereas "plausibility" is the idea that an alleged association should be supported by the substantive knowledge, "coherence" is the idea that an alleged association should not conflict with existing substantive knowledge. *See* Frank C. Woodside, III and Allison G. Davis, The Bradford Hill Criteria: The Forgotten Predicate, 35 T. Jefferson L. Rev. 103, 123 (2013). Experimental evidence that is generally used to support a causal relationship stems from animal or clinical research which identify problems, gather data, formulate hypotheses, and then empirically test those hypotheses. *See generally Trach v. Fellin*, 817 A.2d 1102 (Pa. Super. Ct. 2003). Finally, while analogy refers to the concept that if one drug causes a specific disease, it can be analogized to another drug, a reliable methodology must still be utilized in drawing such a comparison. *See McClain v. Metabolife Intern., Inc.*, 401 F.3d 1233, 1241 (11th Cir. 2005).

burdens created by the discovery proceedings." *Williams v. BASF Catalysts, LLC*, No. CV 11-1754, 2017 WL 3317295, at *4 (D.N.J. Aug. 3, 2017), *objections overruled*, No. CV 11-1754, 2017 WL 4220282 (D.N.J. Sept. 21, 2017) (citing Fed. R. Civ. P. 26 advisory committee's note to 2015 amendment). "The parties and the court have a collective responsibility to consider the proportionality of all discovery and consider it in resolving discovery disputes." *Williams*, 2017 WL 3317295, at *4.

In defining the scope of discovery following the amendment, courts consider the following factors as explicitly set forth in Rule 26(b)(1): "(1) the importance of the issues at stake in the action, (2) the amount in controversy, (3) the parties' relative access to relevant information, (4) the parties' resources, (5) the importance of the discovery in resolving the issues, (6) and whether the burden or expense of the proposed discovery outweighs its likely benefit." *Emplrs Ins. Co. of Wausau v. Daybreak Express, Inc.*, No. 2:16-CV-4269-JLL-SCM, 2017 WL 2443064, at *2 (D.N.J. June 5, 2017). Of course, "[p]roportionality determinations are made on a case-by-case basis with the aforementioned factors, and 'no single factor is designed to outweigh the other factors in determining whether the discovery sought is proportional.'" *Id.* (citing *Bell v. Reading Hosp.*, Civ. No. 13–5927, 2016 WL 162991, at *2 (E.D. Pa. Jan. 14, 2016)).

One of the issues before the Special Master is the PSC's request for additional time prior to submitting their expert reports in order to take fact depositions of current and former employees of Defendants. The PSC produced a list of 62 current or former employees of Defendants who possess important and relevant information necessary for the completion of PSC's expert reports related to general causation. The PSC has conceded that it could likely obtain the necessary information without deposing all of the 62 witnesses prior to the export reports' deadline, however,

a considerable amount of fact depositions is needed for the PSC to obtain the information necessary to complete their expert reports.

The PSC's designation of potential deponents is by no means inconsistent with practice in comparable MDL cases. The PSC provided the Special Master with a detailed list of comparable cases, each involving numerous associated depositions. Exhibit 8 (PSC's Initial Disclosure of Potential Deponents). The simple fact of the matter is that if now is not the time to take the depositions of defendants' fact witnesses, then there is no appropriate time to do so. As in most comparable MDL cases, defendant fact depositions go to the heart of general causation. Specific causation is inextricably interwoven with individual and bellwether plaintiff discovery. To deny plaintiffs a full and fair opportunity to discover their case before general causation reports are due is to turn the rulebook upside down.

On February 6, 2018, The Special Master filed his Proposed CMO finding that there is "a middle ground" between Plaintiffs' request for 62 fact depositions and Defendants' request that no depositions be allowed. Dkt. No. 4173 at 3. The Special Master conceded that it is "reasonable that Plaintiffs may need to depose someone with knowledge on these topics to assist the experts in forming and finalizing opinions." Dkt. No. 4173 at 3–4. The Special Master ultimately found that "62 depositions prior to serving expert reports is unreasonably burdensome and would be excessively time consuming." Dkt. No. 4173 at 4. The Special Master's "middle ground" between the list of 62 fact depositions provided by the PSC and Defendants' objecting to any fact depositions being conducted was his recommendation that a single Rule 30(b)(6) witness be permitted per defendant. Dkt. No. 4173. Thus, the Special Master struck the PSC's list of deponents in its entirety. Dkt. No. 4173 at 4.

While the Court has apparently interpreted the Special Master's proposed ruling to be less restrictive than a literal reading may suggest, commenting during the February 7, 2018 Status Conference that it was unlikely that Defendants would be able to produce a single witness to testify about all of the subjects within the four areas of testimony being permitted, the PSC objects to the Proposed CMO as impermissibly restricting the scope of discovery.

As noted above, The Special Master's Proposed CMO should be reviewed *de novo.* The balance that the Special Master attempted to strike, between the 62 witnesses that the PSC would like to depose and the zero depositions that Defendants believe are needed, or a single Rule 30 (b)(6) witness per Defendant is not a fair and proportional balance. Clearly one Rule 30(b)(6) witness per Defendant does not meet the requirements of proportionality to the needs of the case, nor is it a fair "middle ground."

As the PSC has repeatedly informed the Court, this case involves facts that span decades. The likelihood of Defendants being able to produce a single Rule 30 (b)(6) witness to testify about all of the relevant facts and information concerning general causation issues is unrealistic. Proportionality requires striking a more even handed balance and permitting the PSC to take more depositions than the Special Master's Proposed CMO facially authorizes.

D. Additional Areas of Discovery/Deposition Testimony That the PSC Should Be Permitted to Take

As noted above, The Special Master's Proposed CMO defines four areas for the PSC's Rule 30 (b)(6) depositions of Defendants. However, in addition to these four categories, the PSC has identified the following categories of information which are relevant to *Daubert* and the application of, among other things, the Bradford Hill criteria. Therefore, the PSC should be permitted to inquire about: (1) Defendants' bases for statements about the biologic plausibility of talc migrating to ovaries; (2) information relied upon by Defendants to support their position that

talc products do not cause ovarian cancer; and (3) communications between Defendants related to the link between their respective products and cancer.

As demonstrated through specific examples below, the Special Master's limiting of Plaintiffs' ability to review documents and take specific depositions prevents Plaintiffs from obtaining the types of relevant and admissible evidence that would assist Plaintiffs' experts under the *Daubert* standards cited above.

For example, Defendant Johnson & Johnson ("J&J") has produced in discovery in this case document JNJ 000460665-673[6] that bears on the general causation issue, but may be a document that the PSC is precluded from inquiring about at a Rule 30(b)(6) deposition because of limitations set by the Special Master's Proposed CMO. In essence, this document states that a Pharmacovigilance ("PV") physician has reviewed cases of ovarian cancer. It says that there is an "established criteria" for causation at J&J (though this was done in a PV context). The limited scope of Rule 30 (b)(6) depositions that the Special Master's Proposed CMO permits may deprive or deny the PSC from discovering what that "established criteria" was, yet whatever the "established criteria" may have been clearly relates to the general causation issue that the PSC's expert reports must address.

This document also states that:

[redacted]

[6] A copy of this document is attached hereto as Exhibit 9.

Id. at JNJ 000460666.

While the document is a bit confusing, its "Literature" section states that the literature acknowledges that migration of talc following perineal application from the genital area through the upper genital tract to the ovaries is biologically plausible. *See, Id.* at JNJ 000460668. Defendants have consistently argued, as they did in their Science Day presentation before the Court, that talc does not migrate up the vagina to the ovaries. Further, in the "Conclusion" section, the following statement is made:

[redacted]

Id.

Another safety surveillance document,[7] dated April 2012, contains J&J's analysis of a reported case of ovarian cancer following the use of Johnson's Baby Powder. Exhibit 10, at 20. The analysis contained therein omits the 2006 IARC conclusion that talcum powder is a possible carcinogen, stating instead that "talc not containing asbestos 'not classifiable as to carcinogenicity' to humans." Moreover, the analysis is absent of any consideration of scientific and medical literature published between 2006 and 2012.

The PSC needs to be able to explore issues like those raised in these illustrative documents, to be able to provide their experts with information relevant to the general causation question, and to insulate the PSC's experts from unfair cross-examination about the reliability of their opinions.

[7] A copy of this document, JNJTALC000306286, is attached hereto as Exhibit 10.

III. Conclusion

For the foregoing reasons, the PSC objects to the entry of the Proposed CMO drafted by The Special Master. The PSC continues to object that depositions be limited to 30(b)(6) depositions only. However, the PSC understands the Court's ruling as stated during the February 7, 2018 Status Conference, and therefore, requests that the Court modify the Special Master's Proposed CMO to provide for a more expansive scope of Rule 30(b)(6) depositions. Further, the PSC urges the Court to stay a ruling on the PSC's request for an extension of time to complete their document review considering the PSC's expectation that the document review will be completed by the time the negotiation of the Rule 30(b)(6) notices is complete and the deposition protocol order is finalized and entered.

Date: February 20, 2018

Respectfully Submitted,

s/ Michelle A. Parfitt
Michelle A. Parfitt
ASHCRAFT & GEREL, LLP
4900 Seminary Road, Suite 650
Alexandria, VA 22311
Telephone: 703-931-5500
Email: mparfitt@ashcraftlaw.com

s/ P. Leigh O'Dell
P. Leigh O'Dell
BEASLEY, ALLEN, CROW,
METHVIN, PORTIS & MILES, PC
218 Commerce Street
Montgomery, AL 36104
Telephone: 334-269-2343
Email: leigh.odell@beasleyallen.com

s/ Christopher M. Placitella
Christopher M. Placitella
COHEN PLACITELLA ROTH, PC
127 Maple Avenue
Red Bank, NJ 07701
Telephone 888-219-3599
Email: cplacitella@cprlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on February 20, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

Respectfully submitted,

s/ P. Leigh O'Dell

P. Leigh O'Dell
BEASLEY, ALLEN, CROW,
METHVIN, PORTIS & MILES, PC
218 Commerce Street
Montgomery, AL 36104
Telephone: 334-269-2343
Email: leigh.odell@beasleyallen.com

Plaintiffs' Co-Lead Counsel